REMARKS

Original claims 1-23 were of record pending in this application. Claims 8 and 11-19 have been withdrawn from consideration, and claim 2, 3 and 20 are canceled. Therefore, claims 1, 4-7, 9, 10, and 21-23 are currently pending in this application.

Claim Objections

Claim 5 stands objected to because the abbreviation TPGS as not spelled out. Claim 5 has been amended to address this objection.

Claim Rejections

35 USC 112

Claims 1-7, 9, 10 and 20-23 stand rejected under 35 USC §112, second paragraph as bein indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner rejected independent claims 1, 20 and 21 for reciting the phrase "substantially maintaining damage to pathogen nucleic acid" which the Examiner felt was unclear as to how long the damage was to be maintained. To address the Examiner's rejection, claims 1and 21 have been amended, claim 20 has been cancelled. Support for these amendments is found on page 8, line 1, of Applicants specification. Withdrawal of this rejection is respectfully requested.

Claims 1-7, 9, 10 and 20-23 also stand rejected under 35 USC §112, first paragraph, written description, as failing to comply with the written description requirement. The Examiner feels the specification lacks description with respect to structures and/or functional properties related to those structures of any "damage", any "pathogen", any "blood component", any "photosensitizer" and any "light".

Claim 1 has been amended to recite the phrase "permanent damage." Permanent damage is defined on page 3, line 20 of Applicants specification as "permanent damage means that the inactivated pathogens are unable to re-activate upon storage or upon infusion into a recipient."

Claim 1 has also been amended to specify that the photosensitizer is riboflavin.

"Blood component" is defined on page 1, line 9. "Whole blood collected from volunteer donors for transfusion into recipients is typically separated into its components: red blood cells, white blood cells, platelets, plasma and plasma proteins."

"Pathogens" are defined on page 2 line 19. "Pathogens may be undesirable cells such as white blood cells or may include microorganisms such as bacteria, parasites or viruses." Example 5 describes the process of damaging the nucleic acids of bacteria (E. coli), Example 5 describes the process of damaging viruses (lambda phage) and Examples1-3 describes the process of damaging the nucleic acids of undesirable cells (white blood cells). Claim 1 has been amended to reflect that pathogens may be white blood cells, bacteria or viruses.

"Light" used is either visible or UV (see FIGS. 1 and 2) and Example 1. Claim 1 has been amended to reflect this.

With respect to the Examiner's assertion that the specification does not describe the claimed process of "substantially maintaining the damage to the pathogen nucleic acid after transfusion into a recipient" claim 2 has been deleted.

Claims 1-7, 9, 10 and 20-23 also stand rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. The Examiner feels that the examples set forth in the specification are not sufficient for one of ordinary skill in the art to make and/or use the invention.

On page 9 of the office action the Examiner states that the specification does not support the broad scope of the process as claimed in claim 1 because the specification does not establish A.) adequate guidance with respect to practicing the claimed process with all pathogens B.)

guidance with respect to all modifications and derivatives of all photosensitizers comprising riboflavin C.) guidance with respect to practicing the claimed process using all types of fluids including but not limited to liquids (i.e. hydrophobic solvent, aqueous solvent, organic media etc) gases and plasmas D.) adequate guidance with respect to practicing the claimed process using the light at all wavelengths and all intensities E.) guidance with respect to practicing the claimed process that results in all types of nucleic acid damages including but not limited to deaminators, free-radical induced oxidations, single or double strand breaks, inter and intra strand crosslinks, methylations, alkylations, intercalations etc. F.) guidance with respect to practicing the claimed process that can maintain the damage caused to the pathogen nucleic acid for an unspecified duration G.) any guidance with respect to practicing the claimed process that substantially maintains the damage to the pathogen nucleic acid after transfusion into a recipient; and H.) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

To address the Examiner's enablement rejection A.), as discussed above, claim 1 has been amended to specify that pathogens include pathogenic white blood cells, bacteria and/or viruses. With respect to the Examiner's rejection B.), claim 1 has also been amended to specify that the photosensitizer is riboflavin. To address the Examiner's rejection C.), claim 1 and 21 have been amended to reflect that the fluid contains pathogenic white blood cells, bacteria and/or viruses which may be contained in blood components. Applicants have amended claim 1 and 21 as discussed above (Examiner's rejection D.) to recite that the light is in a visible or UV range. To address the Examiner's rejection E.), Applicants have amended claim 1 and 21 to reflect that the nucleic acid damage is caused by fragmentation of the nucleic acids. To address the Examiner's rejection F.), as discussed above, claim 1 has been amended to recite that "the permanent damage to pathogen nucleic acid caused by the photosensitizer and light is maintained over time such that the pathogen will not reproduce." As discussed above, claim 2 has been deleted. This should address the Examiner's rejection G.).

35 USC §102

Claims 1, 3, 6, 7, 10, 20, 21 and 23 are rejected under 35 USC §102(e) as being anticipated by Goodrich et al (US patent no. 6258577).

Applicant disagrees that the present invention lacks novelty over the Goodrich reference. The present invention describes an effect of riboflavin and light which is broader than pathogen reduction alone. The Goodrich reference does not address whether strand breaks in the nucleic acids of pathogens is permanent, as claimed in Applicants independent claims 1 and 21. As shown in Figs. 1-3b, the present invention describes a process that not only has an effect on the reproduction of pathogens, but has metabolic (Figs. 3a-b) and immunostimulatory (see Figs 1-2) effects as well. These effects are not disclosed in Goodrich.

As described in Example 1, jurkat cells (which are a model for T-lymphocytes) were unable to produce cytokines after exposure to riboflavin and light. Cytokine production is a measure of cell viability. This is not disclosed in Goodrich. Example 2 describes changes in cellular metabolism upon exposure to riboflavin and light. Cells exposed to riboflavin and light are unable to respire and consume oxygen. Cells that are not viable do not reproduce. This is also not disclosed in Goodrich.

Double patenting

To overcome the non-statutory double patenting rejection over claims 1-18 of the Goodrich patent, Applicants are filing with this response a terminal disclaimer.

It is believed an extension of time fee is required for this filing. The Commissioner is authorized to charge the fee to Deposit Account 032316.

If there are any questions, or if prosecution can be expedited in any manner by a telephone conference, the Examiner is urged to call Applicants representative at the below telephone number.

Respectfully submitted,

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Date

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